

R E M A R K S

Entry of this Amendment and reconsideration of this application as amended are respectfully requested.

Claims 1-28 and new claims 29 and 30 are pending in this application.

Claims 1, 3, 7-15, 20, 23 and 25 are amended. No new matter is introduced by the changes to the claims. Unless an argument is made below in support of the patentability of each of these claims over the cited prior art, the changes to these claims do not relate to patentability.

Claim Rejections-35 U.S.C. 102/103

Claims 1-7, 9-11 and 13-28 are rejected in view of Stevens (U.S. Pat. No. 4,811,743). Claims 8 and 12 are rejected in view of Stevens and Majlessi (U.S. Pat. No. 4,842,583).

The Examiner's rejections are respectfully traversed in view of changes to independent claims 1, 7, 15 and 23.

Claim 1 is directed to a guidewire for guiding an irrigating tube into and through a body cavity which includes an elongate, resilient shaft adapted to pass in an interior of or along the irrigating tube and a bulbous enlargement arranged at a distal end of the shaft. Claim 23 is directed to an improvement to a body cavity irrigation device including an irrigating tube through which fluid is directed and a guidewire for guiding the irrigating tube into and through a body cavity. The guidewire includes an elongate, resilient shaft adapted to pass in an interior of or along the irrigating tube and a bulbous enlargement arranged at a distal end of the shaft.

In the embodiments set forth in claims 1 and 23, the bulbous enlargement has a diameter which is at least about 0.25 inches and significantly larger than a diameter of the shaft such that when

present in the body cavity, a location of the bulbous enlargement is easily identifiable, and the body cavity around the bulbous enlargement and the bulbous enlargement are together easily graspable through a wall of the body cavity. These features are described in the specification at, for example, page 5, lines 12-17 and page 8, lines 15-17. Further, the feature of the diameter of the bulbous enlargement being significantly larger than the diameter of the shaft is evident from the drawings, e.g., Figs. 1 and 3-5.

An advantage of these features is that they provide the surgeon with the ability to effectively grasp and manipulate the guidewire through the wall of the body cavity. For example, by holding the bulbous enlargement and withdrawing the guidewire from the body cavity, the body cavity is forshortened (accordioned) over the irrigating tube, thereby facilitating advancement of the irrigating tube into and through the body cavity.

Claim 7 is directed to a method for irrigating a body cavity in which an irrigating tube having a distal end, a passage and an opening at or near the distal end which communicates with the passage, is slid over or along a guidewire and then fluid is directed through the passage defined by the irrigating tube while the irrigating tube is situated over or along the guidewire such that the fluid flows from the passage out of the opening at or near the distal end of the irrigating tube into the body cavity to irrigate the body cavity.

Similarly, claim 15 is directed to a colonic irrigation device including an irrigating tube including a distal end, a passage and an opening at or near the distal end which communicates with the passage, and means for providing a flow of fluid through the passage defined by the irrigating tube while the irrigating tube is situated over or along the guidewire such that the fluid flows from

the fluid flow providing means into the passage, through the passage and then from the passage out of the opening at or near the distal end of the irrigating tube into the colon to irrigate the colon.

The features of claims 7 and 15 are described in the specification at, for example, page 7, lines 6-9 and page 10, lines 7-22.

The cited prior art does not disclose, teach or suggest all of the features of the present claimed invention.

Stevens shows a guidewire 50 for a balloon catheter used in conducting an angioplasty procedure to enlarge an obstructed blood vessel and has a bulbous enlargement at a distal tip 56 (see Fig. 4). In such procedures, the guidewire is guided to the location at which the blood vessel is obstructed, the catheter is routed over the guidewire and then an inflatable balloon portion of the catheter is inflated (see col. 2, line 46 to col. 3, line 2 with reference to Fig. 1).

In contrast to the embodiments of the invention set forth in claims 1 and 23, the bulbous enlargement 56 of the Stevens device does not have a diameter of at least 0.25 inches. Rather, in view of the use of the guidewire for guiding catheters through blood vessels, its diameter must be significantly less.

Another difference between these claimed embodiments of the invention and the guidewire of Stevens is that for the guidewire of Stevens, when it is present in the blood vessel, a location of the bulbous enlargement cannot be easily identified and the body cavity around the bulbous enlargement and the bulbous enlargement cannot be easily grasped through a wall of the body cavity. Rather, the guidewire 50 of Stevens has a sheath 54 around the shaft 52 which has substantially the same diameter as the bulbous enlargement (distal tip 56) so that it is not possible to discern the location

of the bulbous enlargement relative to the shaft through the wall of the body cavity into which the guidewire is routed. As such, a surgeon could not effectively grasp the guidewire 50 and manipulate it through the bowel wall.

Moreover, it would not have been obvious to increase the diameter of the guidewire as suggested by the Examiner since the guidewire of Stevens is designed for use in blood vessels which differ by an order of magnitude from body cavities which are irrigated as in the invention, e.g., the colon. That is, one skilled in the art would not have considered using a significantly smaller blood vessel guidewire for guiding an irrigating tube into and through a body cavity which is irrigating, such as the colon.

In contrast to the embodiments of the invention set forth in claims 7 and 15, the catheter of Stevens does not include a distal end, a passage and an opening at or near the distal end which communicates with the passage such that fluid flows from the passage out of the opening into the body cavity to irrigate the body cavity. Rather, Stevens shows a balloon catheter 10 having an inflatable portion 14 which is inflated whereby the inflating medium does not flow out of the catheter. Indeed, such outflow would frustrate the purpose of the inflating medium which is to widen the passageway into which the catheter is routed (see col. 2, lines 59-63).

In addition, Stevens should be considered non-analogous art to the claimed invention because it does not relate to any "irrigation" of a body cavity. Rather, Stevens relates to a guidewire for a catheter having an inflatable portion and thus fluid must be retained therein without exiting the catheter. By contrast, the invention relates to a guidewire for guiding an irrigating tube wherein irrigating fluid flows through the irrigating tube and along or over the guidewire to exit the

irrigating tube in order to irrigate the body cavity. These concepts are substantially different to the extent that one skilled in the art of irrigating device guidance apparatus would not automatically consider the art of catheter guidance apparatus to be a related art.

Majlessi shows a colonic irrigation tube 10 but does not disclose use of a guidewire that can be passed through a body cavity. Thus, Majlessi cannot teach or suggest the combined use of a guidewire and irrigating tube as set forth in the claimed embodiments.

In sum, Stevens and Majlessi taken individually or in combination do not disclose, teach or suggest all of the features of the present claimed embodiments.

In view of the foregoing, it is respectfully submitted that the Examiner's rejections of claims 1-28 have been overcome and should be removed and that the present application is in condition for allowance.

New Claims

Claims 29 and 30 are added and are directed to the feature of the passage between the shaft of the guidewire and irrigating tube being defined by surfaces thereof (as shown in Fig. 2). This feature is not disclosed in the prior art of record because Stevens shows use of the guidewire having a sheath around the shaft so that the outer surface of the shaft of the guidewire cannot define a passage.

An additional fee of \$50 is required for the presentation of claims 29 and 30 and payment is being made simultaneously herewith.

U.S. patent application Ser. No. 10/702,303
Response to Office Action dated Aug. 24, 2007
Amendment dated November 26, 2007

An early and favorable action on the merits of the invention
is earnestly solicited.

Respectfully submitted,

/Brian Roffe/

Attorney for Applicant
Brian Roffe
Reg. No. 35,336

Brian Roffe
11 Sunrise Plaza, Suite 303
Valley Stream, New York 11580-6111
Tel. No. (516) 256-5636
Fax No. (516) 256-5638